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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,680	01/25/2002	Teddy Kosoglou	CV01492K	9993

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
HUI, SAN MING R	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
03/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/056,680	**Applicant(s)** KOSOGLOU ET AL.	
	Examiner San-ming Hui	**Art Unit** 1617	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 1/9/07 and 1/11/07 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *1* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *09 January 2007*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3,35-37,42-45 and 47*.
   Claim(s) withdrawn from consideration: *4-10,12-17,21-34,38-41 and 48*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

San-ming Hui
Primary Examiner
Art Unit: 1617

Continuation of 3. NOTE: The proposed amendments filed 1/9/2007 change the scope of the invention and at the same time, not considered to be allowable (See discussion below), and thus, the proposed amendments filed 1/9/2007 will not be entered..

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments averring the unexpected results, along with the declaration by Dr. Chintala, filed January 9, 2007 have been consdiered, but are not found persuasive. Examiner notes that it is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. Ex parte Gelles, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" In re Lohr, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, In re Linder, 173 USPQ 356 (CCPA 1972). In the instant case, the dosage claimed is not commensurate with the dosage used in the experiment. There is only one single dosage used for aspirin and one dosage for ezetimibe and yet the claims recite a very large range of both agents. It is not clear how one single dosage can extrapolate to a vast range of active. There is no rationale as to how the dosage of ezetimibe be expanded to a broad as claimed. The rationale for expanding the dosage of aspirin is not convincing. Various references were cited in attempt to provide reasoning for the range of dosage recited in the claims; however, the dosage range is not for the normal dosage range for antiplatelet activity. Rather, it should be corresponding to the unexpected benefit of antiplatelet activities, and not the normal antiplatelet activities of aspirin. Applicant's arguments averring the lack of motivation provided by the cited priro arts hav ebeen considered, but are not found persuasive. As discussed many times before, the motivation to combine the teachings of the cited prior arts is based on the fact that the herein claimed agents are known to be useful in reducing the risk of cardiovascular diseases such as atherosclerosis. Therefore, combining these agents into a single composition useful for the very same purpose would be considered obvious, absent evidence to the contrary (See In re Kerkhoven 205 USPQ 1069). Examiner notes that the basis to combine is not based on the agents having same mechanism of action. The basis is rather they are known to have the same therapeutical use in the art. Applicant's remarks with regard to some of the claims do not require the presence of an optional agent such as statin is acknowledged. Examiner notes that although some of the claims do not require statin, they do not exclude them neither. Therefore, possessing the teachings of the cited prior arts, one of ordinary skill in the art would have been motivated to combine the herein claimed actives into a single composition useful for the very same purpose (See In re Kerkhoven 205 USPQ 1069)..